

REMARKS

Claims 1, 3-17 and 31-78 are pending in the present application. By virtue of this amendment, claim 16 and 56 have been canceled, claims 1, 4, 9, 13, 17, and 67 have been amended. New claims 79-90 have been added. Accordingly, claims 1, 3-15, 17, 31-55, and 57-90 are currently under consideration.

With respect to claim amendments and cancellation, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Withdrawn Rejection

Applicants acknowledge with appreciation that the rejection of claims 1, 3-17, 29, 31-33, 39-41, 47-49, and 55 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kunz (5,733,925) in view of Westesen (6,197,349) is withdrawn in view of the amendments made in the response to Office Action filed on December 20, 2006.

Information Disclosure Statement

Applicants respectfully request that the Examiner consider the Information Disclosure Statement submitted on February 26, 2007 and the Information Disclosure Statement submitted herewith.

Claim Rejections under 35 U.S.C. §103(a)**Rejections over Desai, Kinsella, and Westesen**

Claims 1, 3-17, 31-33, 38-41, 46-49, 54-57 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Desai et al (5,439,686) in view of Kinsella et al (5,616,608) in further view

of Westesen et al (6,197,349) or over Kinsella in view of Desai in further view of Westesen. Applicants respectfully traverse.

Solely in an effort to expedite prosecution, claims 1, 9, and 17 have been amended to recite “wherein the effective amount of the composition is delivered in less than about 30 minutes.” Applicants respectfully submit that Desai, Kinsella, and Westesen, either alone or in combination, do not teach each and every limitation of the present claims.

The Examiner acknowledges that Desai does not teach the claimed methodology of treating non-cancerous cell proliferation in blood vessels. Page 3 of the March 8, 2007 Office Action.

The Examiner states that Kinsella teaches a method of treating atherosclerosis or restenosis using microtubule stabilizing agent such as taxol or taxol derivatives. Kinsella, however, does not teach delivery of an effective amount of a drug composition in less than about 30 minutes for treating atherosclerosis or restenosis. Instead, Kinsella teaches continuous IV infusion of taxol over a 24 hour period, or even over 5-7 days. *See, e.g.*, column 5, lines 43-57 of Kinsella.

Furthermore, Kinsella teaches that severe allergic reactions and cardiac arrhythmias have been observed following administration of taxol, and that the incidence and severity of the problems are affected by the dosage and rate of taxol infusion. Column 3, lines 10-30 of Kinsella. To overcome these problems, Kinsella teaches that “infusion time up to 24 hours have been used in treatment with taxol to decrease the incidence of toxicity and allergic reaction to the drug.” Column 3, lines 28-30 of Kinsella. Kinsella also teaches that use of local sustained delivery may eliminate problems of systemic toxicity. *See, e.g.*, column 11, lines 10-30. Kinsella further teaches that water soluble taxol derivatives can be administered in a dosage schedule analogous to what is given for taxol. Column 6, lines 21-25 of Kinsella. Kinsella therefore teaches away from administering an effective amount of a drug composition (such as paclitaxel) in less than about 30 minutes for treating non-cancerous cell proliferation in blood vessels.

Westesen is cited as allegedly teaching use of an amorphous form of a poorly water-soluble drug to provide better solubility and bioavailability of the poorly water-soluble drug than utilizing a

crystalline form. Westesen does not disclose method of treating non-cancerous cell proliferation in blood vessels, or delivering an effective amount of a drug composition in less than about 30 minutes for such purpose.

Applicants thus respectfully submit that Desai, Kinsella, and Westesen, alone or in combination, do not disclose all claimed limitations in claims 1, 9, and 17. Further, Kinsella teaches away from the claimed invention. Accordingly, Applicants respectfully submit that these references do not render the claims 1, 9, and 17 obvious. Similarly, claims 3-8, 10-15, 31-33, 38-41, 46-49, and 54-57, all of which directly or indirectly depend from claims 1, 9, and 17, are not rendered obvious by the cited references.

Applicants respectfully request that the rejection be withdrawn.

Claims 34, 35, 42, 43, 50-51, which depend from claims 1, 9, or 17, are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Desai et al (5,439,686) in view of Kinsella et al (5,616,608) in view of Westesen et al (6,197,349) in further view of Hunter (5,994,341). Applicants respectfully traverse.

As discussed above, claims 1, 9, and 17 have been amended to recite “wherein the effective amount of the composition is delivered in less than about 30 minutes.” Applicants respectfully submit that Desai, Kinsella, Westesen, and Hunter, either alone or in combination, do not teach each and every limitation of claims 34, 35, 42, 43, 50-51, which depend from claims 1, 9, or 17.

Desai, Kinsella, and Westesen are discussed above. Hunter is cited as allegedly teaching that both epothilone and paclitaxel disrupt microtubule function. Hunter does not cure the deficiencies discussed above. Accordingly, Applicants respectfully submit that the cited references do not render the claims obvious.

Applicants respectfully request that the rejection be withdrawn.

Claims 36-37, 44-45, 52-53, which depend from claims 1, 9, or 17, are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Desai et al (5,439,686) in view of Kinsella et al (5,616,608) in view of Westesen et al (6,197,349) in further view of Gregory (Transplantation, vol. 59, pp. 655-661, 1995). Applicants respectfully traverse.

As discussed above, claims 1, 9, and 17 have been amended to recite “wherein the effective amount of the composition is delivered in less than about 30 minutes.” Applicants respectfully submit that Desai, Kinsella, Westesen, and Gregory, either alone or in combination, do not teach each and every limitation of claims 36-37, 44-45, 52-53, which depend from claims 1, 9, or 17.

Desai, Kinsella, and Westesen are disclosed above. Gregory is cited as allegedly teaching that rapamycin is an immunosuppressant which has an antiproliferative action that is useful in the treatment of arterial thickening after injury such as angioplasty. Gregory does not cure the deficiencies discussed above. Accordingly, Applicants respectfully submit that the cited references do not render the claims obvious.

Applicants respectfully request that the rejection be withdrawn.

Rejections over Hunter, Yapel, and Westesen

Claims 1, 3, 6-12, 15-17, 31-35, 38-43, 46-51, 54-66, 69-78 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hunter et al (5,716,981) by itself or in view of Yapel (4,147,767) in further view of Westesen et al (6,197,349). Claims 4-5, 13-14, 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al (5,716,981) by itself or in view of Yapel (4,147,767) in view of Westesen et al (6,197,349) in further view of Kinsella et al (5,616,608). Applicants respectfully traverse.

As discussed above, claims 1, 9, and 17 have been amended to recite “wherein the effective amount of the composition is delivered in less than about 30 minutes.” Applicants respectfully submit that Hunter, Yapel, Westesen, and Kinsella, either alone or in combination, do not render the present claims obvious.

The Examiner acknowledges that Yapel, Hunter, and Westesen do not specify dosing amount and dosing cycles of the drug composition, and relies on Kinsella as providing the dosage amount and dosing cycle. Page 10 of the March 8, 2007 Office Action. As discussed above, Kinsella does not teach delivery of an effective amount of a drug composition in less than about 30 minutes. Furthermore, as discussed above, Kinsella teaches away from the dosing regime presently claimed. Accordingly, Applicants submit that the references, alone or in combination, do not teach all the claimed elements of the present invention, and thus do not render the present claims obvious.

Applicants respectfully request that the rejection be withdrawn.

Claims 36-37, 44-45, 52-53, which depend from claims 1, 9, or 17, are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hunter et al (5,716,981) by itself or in view of Yapel (4,147,767) in view of Westesen et al (6,197,349) in further in view of Marx (Circ. Res. Vol. 76, pp. 412-417, 1995). Applicants respectfully traverse.

As discussed above, claims 1, 9, and 17 have been amended to recite “wherein the effective amount of the composition is delivered in less than about 30 minutes.” Applicants respectfully submit that Hunter, Yapel, Westesen, and Marx, either alone or in combination, do not teach each and every limitation of claims 36-37, 44-45, 52-53, which depend from claims 1, 9, or 17.

Hunter, Yapel, and Westesen are discussed above. Marx was cited as allegedly teaching rapamycin as an inhibitor of smooth muscle cells in the abnormal proliferation of restenosis. Marx does not cure the deficiencies discussed above. Accordingly, Applicants respectfully submit that the cited references do not render the claims obvious.

Applicants respectfully request that the rejection be withdrawn.

Double Patenting Claim Rejections

Claims 1, 3-41, 46-49, 52-78 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-7, 11-20, 44-48 of

copending Application No. 11/544,242 in view of Kinsella. Claims 1, 3-17, 31-32, 38-40, 46-48, 54-78 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1, 5-13, 16-17, 21, 24 of copending Application No. 11/594,417 in view of Kinsella. Claims 1, 5-13, 16-17, 21, 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-2 and 5-18 of copending Application No. 11/359,286 in view of Kinsella.

Applicants respectfully request that these provisional rejections be held in abeyance until the Office has made a determination of otherwise allowable claims in the present application or in copending Application Nos. 11/544,242, 11/594,417, or 11/359,286.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 420052000127. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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